UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/074,497	02/11/2002	Kenneth B. Kirby	2237.006	8128

21917 7590 07/08/2003

MCHALE & SLAVIN, P.A.
2855 PGA BLVD
PALM BEACH GARDENS, FL 33410

EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 07/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/074,497	Applicant(s) KIRBY ET AL.	
	Examiner Isis Ghali	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-41* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The receipt is acknowledged of applicants' drawing, and specification, both filed 07/01/2001; and change of address, filed 08/29/2002.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-38, drawn to transdermal delivery device comprising active agent solute in a solvent.

Group II, claim(s) 39-40, drawn to method of making a transdemal delivery device.

Group III, claim(s) 41, drawn to method of selecting the active ingredients and amounts of a transdemal delivery device.

2. The inventions listed as Groups I, II and III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the transdermal delivery device of Group I can be made by a process other than the process of Group II, such as conventional method of mixing with solvent and evaporating the solvent; and the active ingredients and their amounts can be selected by a method other than the method of Group III, such as per conditions to be treated.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

4. The species and the claims correspond to the species are as follows:

1) Embodiment wherein the transdermal delivery system includes an active agent solute in a solvent , claim 1;

2) Embodiment wherein the transdermal delivery system comprises one solvent modifier, claim 2;

3) Embodiment wherein the transdermal delivery system comprises a solute modifier, claim 3;

4) Embodiment wherein the transdermal delivery system includes solute modifier and solvent modifier, claim 4;

5) Embodiment wherein the transdermal delivery system includes one compound for stimulating the release of energy, claims 5-7;

6) Embodiment wherein the transdermal delivery system includes solvent modifier and compound for stimulating the release of cellular energy, claim 8;

7) Embodiment wherein the transdermal delivery system includes solute modifier and compound for stimulating the release of cellular energy, claim 9;

8) Embodiment wherein the transdermal delivery system includes solute modifier, solvent modifier and compound for stimulating the release of cellular energy, claim 10;

9) Embodiment wherein the transdermal delivery system includes skin stabilizer composition, claim 11;

10) Embodiment wherein the transdermal delivery system includes solvent modifier and skin stabilizer, claim 12;

11) Embodiment wherein the transdermal delivery system includes solute modifier and skin stabilizer, claim 13;

12) Embodiment wherein the transdermal delivery system includes solvent modifier, solute modifier, and skin stabilizer, claim 14;

13) Embodiment wherein the transdermal delivery system includes one compound for stimulating the release of energy and skin stabilizer, claim 15;

14) Embodiment wherein the transdermal delivery system includes permeability modifier, claim 16;

15) Embodiment wherein the transdermal delivery system comprises one solvent modifier and permeability modifier, claim 17;

16) Embodiment wherein the transdermal delivery system includes solute modifier, solvent modifier and permeability modifier, claim 18;

17) Embodiment wherein the transdermal delivery system includes solute modifier, solvent modifier, compound for stimulating the release of cellular energy and permeability modifier, claim 19;

18) Embodiment wherein the transdermal delivery system includes solvent modifier, solute modifier, skin stabilizer and permeability modifier, claim 20;

19) Embodiment wherein the transdermal delivery system includes one compound for stimulating the release of energy, skin stabilizer and permeability modifier, claim 21;

20) Embodiment wherein the transdermal delivery system comprises a solute modifier and permeability modifier, claim 22;

21) Embodiment wherein the transdermal delivery system includes solute modifier, compound for stimulating the release of cellular energy and permeability modifier, claim 23;

22) Embodiment wherein the transdermal delivery system includes solute modifier, skin stabilizer, and permeability modifier, claim 24;

23) Embodiment wherein the transdermal delivery system includes capillary dilator, claim 25;

24) Embodiment wherein the transdermal delivery system includes solute modifier, solvent modifier, permeability modifier, and capillary dilator, claim 26;

25) Embodiment wherein the transdermal delivery system includes solute modifier, solvent modifier, compound for stimulating the release of cellular energy, permeability modifier and capillary dilator, claim 27;

26) Embodiment wherein the transdermal delivery system includes one compound for stimulating the release of energy, skin stabilizer, permeability modifier, and capillary modifier, claim 28;

27) Embodiment wherein the transdermal delivery system includes solute modifier, compound for stimulating the release of cellular energy, permeability modifier and capillary dilator, claim 29;

28) Embodiment wherein the transdermal delivery system includes solute modifier, skin stabilizer, permeability modifier, and capillary dilator, claim 30;

29) Embodiment wherein the transdermal drug delivery in clued particular dose and MW of the active agent; claim 31;

30) Embodiment wherein the transdermal drug delivery in clued particular dose and MW of the active agent in the form of patch, claim 36;

31) Embodiment wherein the transdermal drug delivery in clued particular dose and MW of the active agent in the form of liquid, claim 37.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply

must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 1 and 31 are.

5. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the different transdermal compositions have ingredients.

6. Because the above restriction/election requirement is complex, a telephone call to the applicant's agent to request oral election was not made. See MPEP, Sec.812.01.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (703) 305-4048. The examiner can normally be reached on Monday through Thursday from 7:00 AM to 5:30 PM, Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Isis Ghali
Examiner
Art Unit 1615
IG.

Isis Ghali